No. 13-6061

United States Court of Appeals for the Tenth Circuit

PATRICIA CAPLINGER,

Plaintiff-Appellant,

v.

MEDTRONIC, INC., ET AL.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Western District of Oklahoma
in Case No. 5:12-cv-00630-M (Miles-Lagrange, J.)

Brief For The Product Liability Advisory Council, Inc., As *Amicus Curiae* In Support of Appellees

Hugh F. Young, Jr.
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, VA 20191
(703) 264-5300
Of Counsel

Alan Untereiner
Counsel of Record
Donald Burke
ROBBINS, RUSSELL, ENGLERT, ORSECK, UNTEREINER & SAUBER LLP
1801 K Street, N.W.
Washington, DC 20006
(202) 775-4500
auntereiner@robbinsrussell.com

Counsel for the Amicus Curiae

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Amicus Curiae The Product Liability Advisory Council, Inc., does not have a parent corporation, nor does any publicly held corporation own 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES—cont'd

Page(s)

Statutes, Regulations, and Rules

TABLE OF AUTHORITIES—cont'd

Page(s)

Miscellaneous

INTEREST OF THE *AMICUS CURIAE*[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with 107 corporate members representing a broad cross-section of American and international product manufacturers. Its corporate members make and sell a wide array of products, including automobiles, aircraft, electronics, chemicals, pesticides, pharmaceuticals, and medical devices.[2] PLAC's primary purpose is to contribute to the improvement and reform of law in the United States and elsewhere, with an emphasis on the law governing the liability of manufacturers of products.

Toward that end, since 1983 PLAC has filed over 1,000 *amicus* briefs in the state and federal courts, including numerous briefs in this Court. PLAC has participated as *amicus curiae* in all three of the U.S.

---

[1] All parties have consented to the filing of this brief under Rule 29(a) of the Federal Rules of Appellate Procedure.

[2] A list of PLAC's corporate members is attached as Appendix A. Pursuant to Fed. R. App. P. 29(c), PLAC states that no party's counsel authored this brief in whole or in part, and no party, party's counsel, nor other person other than PLAC and its counsel contributed money intended to fund the preparation or submission of this brief. While Appellee Medtronic, Inc., is a corporate member of PLAC, membership is neither necessary nor sufficient to obtain PLAC's *amicus* support. Medtronic made no contribution to the fee paid for this brief (other than its ordinary dues as paid by all corporate members of PLAC). PLAC never accepts funds earmarked for *amicus* briefs.

Supreme Court's preemption decisions involving state efforts to regulate medical devices: *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008), *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996).

This appeal raises issues of considerable importance to PLAC and its members. It presents significant questions concerning the scope of both express preemption under the Medical Device Amendments, 21 U.S.C. § 360k(a), and implied preemption under the Supreme Court's decision in *Buckman*. It also raises an important and recurring question about the standards courts should apply in evaluating, on a motion to dismiss, the threshold legal defense of federal preemption under an express preemption clause that contains an exception for state requirements that are *identical* to the applicable federal requirements (an exception found in many preemption statutes, not just in 21 U.S.C. § 360k(a)). Because federal preemption is an important defense for device and other product manufacturers, PLAC and its members have a strong interest in ensuring that the significant issues raised in this appeal are properly resolved.

STATEMENT

This case arises out of a surgical procedure, performed in 2010 on Plaintiff-Appellant Patricia Caplinger, in which her surgeon elected to use a Class III, prescription medical device known as the Infuse® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device ("Infuse" device), which is manufactured by Defendants-Appellees Medtronic, Inc. and Medtronic Sofamor Danek USA Inc. (collectively "Medtronic"). The United States Food and Drug Administration ("FDA") approved the Infuse device in 2002 for marketing after conducting an exacting and painstaking review of its safety and efficacy in a process known as the premarket approval ("PMA") process, the most rigorous review process that exists for medical devices. As the Supreme Court made clear in *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008), the FDA's approval through the PMA process imposes federal requirements on a medical device's design, manufacture, and labeling that, under 21 U.S.C. § 360k(a), preempt "any" state-law requirements that "relate[] to" the device's "safety or effectiveness" and are not identical to the federal requirements.

In this litigation, Caplinger challenges the Infuse device's

federally required design as unsafe – and its federally required labeling and warnings as inadequate – by advancing a flurry of state-law claims, including claims for strict-liability design defect and failure to warn, negligence, fraudulent misrepresentation, and breach of express and implied warranty. See Appendix of Record Excerpts ("JA"), at 5-41 (amended complaint). In a careful and thoroughly reasoned opinion, the district court correctly granted Medtronic's motion to dismiss the amended complaint on the ground that all of Caplinger's claims were expressly preempted by 21 U.S.C. § 360k(a), impliedly preempted under *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and/or pleaded with insufficient particularity. JA 43-74.

In so ruling, the district court specifically rejected Caplinger's efforts to circumvent the scheme of express and implied preemption recognized in *Riegel* and *Buckman* on the ground that (a) her surgeon had chosen to use the Infuse device in an "off-label" fashion, by implanting it through a posterior, rather than anterior, approach; and (b) Medtronic had allegedly promoted this off-label use, assertedly in violation of federal law, through a variety of actions. Notably, Caplinger made these arguments even though both *Riegel* and

Buckman involved off-label uses of medical devices. In rejecting these contentions, the district court explained that neither the fact that Caplinger's surgeon opted for an off-label use, nor Caplinger's allegations of Medtronic's allegedly unlawful promotion, rendered the state-law requirements she sought to impose on the device identical to the applicable federal requirements or allowed her claims to avoid implied preemption under *Buckman*. JA 56-57, 58-59 & n.4 ("plaintiff's off-label promotion allegations do not somehow turn plaintiff's claims into 'parallel' claims that are not preempted" because any "federal requirement that manufacturers not promote for off-label uses is not genuinely equivalent to the state law requirement[s] that a manufacturer provide adequate warnings to physicians . . . and . . . not produce a product with defective design"), 60-61 (fraudulent misrepresentation claim based on off-label promotion is "clearly preempted under *Buckman*").

INTRODUCTION AND SUMMARY OF ARGUMENT

When Congress in 1976 enacted the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act ("FDCA"), it conferred on the FDA comprehensive new regulatory authority over

medical devices while at the same time taking steps to "prevent" a proliferation of divergent "state requirements from unduly burdening interstate commerce." *Mendes* v. *Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994). Toward the latter end, as well as to preserve the uniformity of the federal regulatory scheme and protect innovations in device technology from being "stifled by unnecessary restrictions," Congress included an express preemption provision intended to serve as a "general prohibition on non-Federal regulation." H.R. Rep. No. 94-853, at 12, 45 (1976).

Consistent with that description, the MDA's express preemption provision is cast in very broad terms. It provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any* requirement –
>
> > (1) which is different from, or in addition to, *any* requirement applicable under this chapter to the device, and
> >
> > (2) which *relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device* under this chapter.

21 U.S.C. § 360k(a) (emphasis added). Subsection (b) of the express preemption clause authorizes the FDA to grant exemptions from

preemption under certain specified conditions.[3]

The MDA's express preemption broadly nullifies "any" state "requirement" – whether newly enacted or preexisting ("establish or continue in effect") – so long as it satisfies three conditions. First, the state requirement must affect "a device intended for human use" – *i.e.*, a medical device. Second, the state requirement must be "different from, or in addition to, any requirement applicable" to the device under the MDA. Third, the state requirement must "relate to" – a deliberately broad phrase – either "the safety or effectiveness of the device," *or* "any other matter included in a requirement applicable to the device under [the MDA]" (another deliberately broad phrase *not* limited to safety and efficacy matters). 21 U.S.C. § 360k(a). States are precluded from imposing "any requirement" that meets these three conditions, unless FDA grants them an exemption from preemption under 21 U.S.C. § 360k(b).

---

[3] See 21 U.S.C. § 360k(b) (FDA may exempt "a requirement . . . applicable to a device intended for human use if – (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or (2) the requirement – (A) is required by compelling local conditions, and (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.").

In *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court held that FDA approval of a medical device through the exacting PMA process imposes requirements on the device with respect to its design, manufacture, and labeling that trigger preemption under Section 360k(a). At the same time, in both *Riegel* and in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), the Court interpreted the phrase "different from, or in addition to" as excluding from Section 360k(a) state requirements that "parallel," or are "identical" to, the applicable federal requirements. *Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495; see also *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 447, 454 (2005) (interpreting a "similarly worded pre-emption provision" to preempt state labeling requirements unless they were "genuinely equivalent" to and "fully consistent with" federal requirements).

In *Buckman*, the Court held that fraud-on-the-FDA claims, even if purportedly dressed up in a plaintiff's complaint as "traditional state tort law" claims, were impliedly preempted by federal law. That decision rested on an interpretation 21 U.S.C. § 337(a), which states that an action "for the enforcement, or to restrain violations, of th[e] [FDCA] shall be by and in the name of the United States." In light of

this "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government," the Court explained that even if, under *Lohr*, "certain state-law causes of action that *parallel* federal safety requirements" would escape *express* preemption under 21 U.S.C. § 360k(a), that "does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Buckman*, 531 U.S. at 352, 353.

The Eighth Circuit has aptly described the combined effect of these Supreme Court decisions on the legal landscape of preemption for medical devices approved through the PMA process:

> *Riegel* and *Buckman* create a *narrow gap* through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

Bryant v. *Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (emphasis altered; internal quotations omitted); see also *Perez* v. *Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (agreeing with this analysis). The district court in this case correctly recognized, and applied, the foregoing principles in concluding that Caplinger's various state-law

claims did not fall within the "narrow gap" remaining after *Riegel* and *Buckman* to escape express and implied preemption (or were otherwise properly dismissed because they were not pleaded with adequate specificity).

In this appeal, Caplinger seeks to advance several arguments of great concern to PLAC because, if accepted, they would convert this "narrow gap" into a veritable Grand Canyon. *First*, she argues – without any discernible basis in the text, legislative history, or purpose underlying the MDA's express preemption clause – that Section 360k(a) simply does not apply in any case involving an "off-label" use of a medical device (or the assertedly unlawful "promotion" of such an off-label use). Since off-label uses are common (and widely regarded by the physicians who recommend and employ them as desirable and beneficial treatment options), acceptance of this argument would threaten to eviscerate the MDA's express preemption clause and undermine Congress's purposes underlying that provision.

Second, and of equal concern to PLAC, Caplinger seeks to overturn the district court's appropriately demanding approach to specificity in the pleading of her various claims, including those that

Caplinger claims escape express preemption under 21 U.S.C. § 360k(a) because they represent "parallel" or "identical" state requirements. If accepted, that argument would deprive medical device manufacturers of much of the value of preemption as a threshold, purely legal defense that can be resolved without the need for burdensome and unnecessary discovery. Such a result would also be directly contrary to the Supreme Court's recent decisions requiring sufficient specificity in pleading to demonstrate a claim's plausible validity as a precondition to permitting the imposition of discovery burdens. For reasons set forth in detail below, both of these arguments by Caplinger should be rejected by this Court, and the judgment below should be affirmed.[4]

[4] PLAC fully agrees with Medtronic's arguments concerning why various of Caplinger's claims are preempted under *Buckman* but, for space reasons, does not discuss implied preemption in any detail in this brief. Moreover, the express preemption and pleading issues addressed herein have implications for PLAC members that operate in a variety of federally regulated industries and are subject to express preemption schemes (including some schemes that, like the MDA, contain exceptions for identical state requirements, see note 7, *infra*).

ARGUMENT

I. There Is No Valid Basis For Engrafting Plaintiff's Proposed Blanket "Off-Label Use" Or "Off-Label Promotion" Exceptions Onto Section 360k(a)

The district court emphatically – and correctly – rejected the proposition that "§ 360k(a) does not preempt any claim that arises out of" either an off-label use of a medical device or "the promotion of an off-label use of a device." JA 58. Those arguments, the court explained, are "inconsistent with the text of § 360k(a)," which focuses on "whether there are federal requirements applicable 'to the *device*[,]'" not whether "there are federal requirements applicable to a particular *use* of a device." *Ibid.* (internal quotation marks omitted). "[N]othing in [§ 360k(a)]," the district court reasoned, "suggests that the preemption analysis somehow depends on" either "how the device is used" or "how the device is being promoted to be used." JA 59 (internal quotation marks omitted).

On appeal, Caplinger challenges this holding in a two-step argument. First, she observes (Br. 6-7, 8, 18, 25, 27-28) that the FDA's approval of a medical device (including the Infuse device) for marketing through the PMA process focuses on the safety and effectiveness of the

indication(s) for use specified on the device's labeling. Second, she asserts (Br. 18, 21, 25, 28) that, *as a consequence of that focus during the approval-for-marketing process*, the PMA process *imposes no requirements* on the design, labeling, or manufacturing of an approved device with respect to any "off-label" uses of the device. See also Caplinger Br. 25 ("The FDA has never approved the device for that use *and hence* has never imposed requirements on the design or labeling of the device for that use.") (emphasis added).

PLAC notes that, according to Medtronic (Br. 19-20), this argument was never raised below and thus has been waived. If this Court were to disagree with that submission and reach the merits of this argument, however, the Court should emphatically reject it. As Medtronic persuasively demonstrates (Br. 20-27), Caplinger's argument suffers from at least four fatal flaws: (1) it is (as the district court held) inconsistent with the language of § 360k(a), which clearly provides that federal preemption is triggered whenever any federal requirement applies "to the *device*," not to a particular "use" of the device; (2) it rests on the false premise that the FDA does not consider off-label uses during the PMA process (and indeed, the FDA during the PMA process

relating to the Infuse device not only considered such uses but also required the device's labeling to include warnings regarding them); (3) it is inconsistent with *Riegel*, which although it involved an off-label procedure held that all of the plaintiff's claims were covered by Section 360k(a) and expressly preempted; and (4) it would undermine Congress's goals underlying the MDA, not only by eviscerating the statutory express preemption clause – and the protection from burdensome, innovation-stifling state regulation which it embodies – but also by allowing lay juries to second-guess the FDA's expert regulatory judgments concerning such matters as the design, manufacture, and labeling of devices approved through the exacting PMA process.

These are more than ample reasons both to reject Caplinger's request that this Court engraft a blanket, unexpressed exception for "off-label" uses (or the promotion of such uses) onto Section 360k(a) and to affirm the district court's decision (assuming, again, that this Court declines to conclude that Caplinger's argument on this score has been waived). As next explained, however, there are at least four additional

or related reasons why Caplinger's arguments should be rejected by this Court.

First, Congress could easily have written the narrower express preemption provision claimed by Caplinger – but it did not. When describing the federal requirements that trigger express preemption, Congress used the deliberately expansive phrase, "*any* requirement applicable under this chapter to the device." 21 U.S.C. § 360k(a)(1) (emphasis added). Moreover, Congress used similar or identical broad phrasing in the exemption provisions. See 21 U.S.C. § 360k(b)(1) (state requirement may be exempted if it is "more stringent than *a requirement under this chapter* which would be *applicable to the device* if an exemption were not in effect") (emphasis added); *id.* § 360k(b)(2)(B) (exemption available if, among other things, "compliance with" state requirement "would not cause the device to be in violation of *any applicable requirement* under this chapter") (emphasis added). Thus, the only prerequisite to triggering preemption under the plain terms of Section 360k is that "any" federal requirement be "applicable" to "the device," which the Supreme Court has described as "device-

specific[ity]." *Riegel*, 552 U.S. at 322; see also *id.* at 323 ("premarket approval is specific to individual devices").

Congress could have, but did not, include the quite distinct limitation of "use-specificity" urged by Caplinger. Thus, Congress could have recast the MDA's preemption clause so that preemption would be triggered only by federal requirements that are "applicable under this chapter to *an approved use of* the device." Congress also could have recast the exemption provision so that it contained similar limitations. But again, Congress did not. Accordingly, there is no basis for excluding from Section 360k, as Caplinger urges, federal or state requirements relating to warnings or promotional activities concerning off-label uses of PMA-approved devices. Such requirements plainly are "applicable" to the device and they obviously "relate[]" to the "safety or effectiveness of the device." 21 U.S.C. § 360k(a)(1), (2). The district court therefore was correct to reject Caplinger's arguments for a blanket "off-label use" or "promotion of off-label use" exception to as "inconsistent with the text of § 360k(a)." JA 58.

Second, PLAC is aware of no evidence in the legislative history of the MDA that would support Caplinger's "off-label" use or "promotion of

off-label use" exceptions to the preemption clause, and Caplinger has cited none. Indeed, the competing, narrower version of the MDA preemption clause contained in the Senate bill (S. 510, 94th Cong., 1st Sess. (1975)), which the conference committee rejected in favor of the broader preemption clause in the House bill (H.R. 11124, 94th Cong., 2d Sess. (1976)), see H.R. Conf. Rep. No. 94-1090, at 40 (1976), is equally lacking in textual support for Caplinger's proposed exception for all "off label" uses. The Senate bill provided in relevant part:

> Sec. 903. (a) Whenever a performance standard pursuant to section 513 or scientific review pursuant to section 514 under this Act is in effect, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling *of such product* which are designed to deal *with the same device* unless such requirements are identical to the Federal requirements.

S. 510, § 704 (emphasis added); see also S. Rep. No. 94-33, at 33 (1975).[5] Notably, the Senate bill, like just like the statutory text that originated in the House bill, in no way limited the federal requirements that would trigger preemption to those involving an approved use or excluded

[5] The reference to "section 514" was to the process for premarket scientific review set forth elsewhere in the Senate bill.

requirements relating to "off-label" uses. And, of course, by opting for the House bill's language, Congress ultimately selected an *even broader* preemption provision for inclusion in the statute. Thus, the language of the MDA's preemption clause extended the category of state warning requirements beyond those contained in the "labeling" (S. 510, § 704) to cover "any" state requirements that "relate[] to the safety and effectiveness of the device" (21 U.S.C. § 360k(a)) – language that easily includes state requirements concerning the promotion of an off-label use through means other than the product's labeling.

Third, recognition of the giant new loophole urged by Caplinger would not only undermine Congress's public-health objectives underlying Section 360k(a) of encouraging innovation, removing burdensome and conflicting state requirements, and preventing lay jurors from second-guessing the FDA's expert regulatory determinations. It could also entangle state courts and juries in "the difficult task," assigned by Congress exclusively to the FDA, "of regulating the marketing and distribution of medical devices without intruding upon [prescribing] decisions" with respect to beneficial and often widespread off-label uses – decisions that, under 21 U.S.C. § 396,

are "statutorily committed to the discretion of health care professionals." *Buckman*, 531 U.S. at 350; see also *Heckler* v. *Chaney*, 470 U.S. 821, 835 (1985) (noting that Congress gave FDA "complete discretion" to decide "how and when" to "exercise[]" the wide range of enforcement tools entrusted to it). Indeed, it takes little imagination to see how allowing lay juries to second-guess the design or labeling of a PMA device with respect to off-label uses could wreak havoc on the FDA's efforts to regulate the labeling or marketing of PMA devices in a way that balances a variety of public health concerns, including the public health benefit of many off-label uses. See *Buckman*, 531 U.S. at 349 (noting that "flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives"). For that reason as well, Caplinger's blanket exceptions for "off-label" uses and "promotion of off-label uses" should be rejected.

Fourth, Caplinger's argument that Medtronic's alleged promotion of off-label uses takes this case outside of the broad reach of the MDA's express preemption clause ignores contrary evidence in the FDA's exemption practice. More specifically, the FDA refused to grant an

exemption (and thus found to be expressly preempted) a state statute regulating advertising, Cal. Health & Safety Code § 26463(m) (1984) (repealed 1995), which made it unlawful "for any person to advertise any drug or device, represented to have any effect in any of the following conditions, disorders, or diseases: * * * (m) diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness." *Ibid.* (emphasis added). According to FDA, this California provision broadly governing "advertising" in any form was preempted "to the extent that it applies to hearing aids." 21 C.F.R. § 808.55(b)(2); see also Final Rule, *Exemption From Preemption of State and Local Hearing Aid Requirements; Applications for Exemption*, 45 Fed. Reg. 67326, 67331-32 (Oct. 10, 1980) (denying exemption for Cal. Health & Safety Code § 26463(m)). The FDA explained that, while federal requirements applicable to hearing aids required that any advertising not be "false and misleading," the California advertising regulation went further by also barring "truthful representations that hearing aids have an effect on hearing loss." 45 Fed. Reg. at 67332. "Section 26463(m) creates a burden on interstate commerce," the FDA explained in denying the exemption, "because the nationwide manufacturer is

forced to either tailor all its advertising to comply with the California requirements or not advertise in California at all." *Ibid.* It is difficult, if not impossible, to square the FDA's refusal to exempt this California statute with Caplinger's argument that state laws governing the promotion or advertising of Class III, PMA-approved devices are not covered by 21 U.S.C. § 360k(a).

When all is said and done, Caplinger's arguments for new "off-label" and "off-label promotion" exceptions to 21 U.S.C. § 360k(a)(1) are but the latest in a long line of efforts by plaintiffs' lawyers to create new loopholes and exceptions – over and above the exceptions enumerated in the statute for identical state requirements and state requirements exempted by the FDA – to the otherwise broad preemption command chosen by Congress. Thus, in both *Lohr* and *Riegel*, the Supreme Court rejected a proposed exception for all state "requirements" that happened to be imposed by common law (as opposed to by state statute or other form of "positive" law). See *Riegel*, 552 U.S. at 323-24; *Lohr*, 518 U.S. at 509-11 (O'Connor, J., joined by Rehnquist, C.J., and by Scalia and Thomas, JJ., concurring in part and dissenting in part); *id.* at 504-05 (opinion of Breyer, J.).

Similarly, the lower courts have declined to adopt other proposed loopholes, such as the argument that the PMA process does not impose any preemptive "requirements" on an approved device because its design, manufacturing, and labeling all "originate" in choices made by the manufacturer. See, *e.g.*, Brief of Appellant Barbara Horn, *Horn* v. *Thoratec Corp.*, No. 02-4597, 2003 WL 24131420, at *35 (3d Cir. May 1, 2003); compare *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (concluding notwithstanding that argument that PMA approval imposes federal requirements that trigger preemption under § 360k(a)(1)). For all the reasons discussed above, this Court should reject this latest attempt to conjure up limits on the broad language of Section 360k(a)(1) where none exist. See also *Mutual Pharmaceutical Co.* v. *Bartlett*, 133 S. Ct. 2466, 2477-78 (2013) (rejecting argument that, in practice, would render preemption defense "all but meaningless"); *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2578-79 (2011) (same).

II. In Upholding The District Court's Ruling, This Court Should Reaffirm The Pleading Standards That Plaintiffs Must Satisfy To Avoid The Dismissal On Preemption Grounds Of Supposedly "Identical" Or "Parallel" State-Law Requirements Under Section 360k(a)

In dismissing Caplinger's complaint, the district court carefully

reviewed each of the various claims she was advancing and correctly concluded that all were expressly preempted by 21 U.S.C. § 360k(a), impliedly preempted under *Buckman*, and/or pleaded with insufficient particularity. JA 43-74. As an initial step in its preemption analysis, the district court correctly noted that "federal medical device preemption is a question of law and may properly be decided on a motion to dismiss prior to any discovery being conducted." JA 70. Next, it summarized the minimum standards that *any* complaint must satisfy in terms of supporting "factual matter" and "facial plausibility" in order to survive a motion to dismiss under *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009), and *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544 (2007). See JA 48.[6]

Finally, the district court went on to describe the additional pleading requirements that are imposed, under the framework articulated in *Riegel*, on a plaintiff such as Caplinger – whose claims are subject to an express preemption defense under the MDA – to show that the state requirements she is seeking to impose on the Infuse

[6] The district court also described the heightened pleading standard applicable to *any* allegations of fraud under Rule 9(b) of the Federal Rules of Civil Procedure. JA 61-62, 63.

device are "different from, or in addition to," the federal design, manufacturing, labeling, and other requirements applicable to that device. JA 50. To "properly allege [such] parallel claims," the district court explained, "the complaint must set forth facts pointing to specific PMA requirements that have been violated." *Ibid.* (internal quotation marks omitted). In addition, the plaintiff "must show that the [state and federal] requirements [involved] are *genuinely* equivalent." *Ibid.* (internal quotation marks omitted). Applying the foregoing standards, the district court correctly concluded that various of Caplinger's claims were expressly preempted because they involved state requirements that were *not* parallel (or were pleaded with insufficient specificity and supporting factual allegations to establish the requisite "genuine[] equivalence").

Although it reached the correct result, the district court at several points in its opinion arguably suggested that the test for the *absence* of such genuine equivalence was whether "a [device] manufacturer could be held liable under the state law without having violated the federal law." JA 50 (internal quotation marks omitted); see also JA 59 n.4 (no genuine equivalence because "[i]t is possible to violate the state law

requirement while complying with the federal requirement and vice versa"). In fact, as we next explain, that formulation may be a good indicator of the lack of genuine equivalence in many cases, but it is underinclusive – and this Court should make that clear, as well as provide much-needed guidance on the required specificity of pleadings in this setting, in affirming the judgment below.

A. The Inquiry Into Equivalence Requires A Careful Comparison Of The Applicable State And Federal *Requirements*

In urging reversal, Caplinger argues that the pertinent state and federal requirements relating to the Infuse device are genuinely equivalent because the former "do not require Medtronic to *do* anything that federal law does not also require." Br. 19 (emphasis added). Elsewhere, she maintains that there is genuine equivalence because "exactly the same *conduct* that violated federal device requirements violated Medtronic's state law duties." Br. 32 (emphasis added). As Medtronic correctly points out (Br. 29-30), however, Caplinger's formulation – and focus on Medtronic's complained-of *conduct* rather than on the applicable legal *requirements* – is mistaken.

To see why that is so, one need only imagine the following hypothetical. Suppose that, through the PMA process, the FDA imposes a design requirement on a device that it contain in a crucial component a wire that is *no longer than five inches*. Suppose as well that, in a design defect claim brought under state law, a plaintiff contends that the device is defective if it includes a wire that is *longer than three inches*. These requirements (no more than five inches long versus no more than three inches) indisputably are "different." Yet a manufacturer that built the device with a *six-inch* wire would be liable under state law for design defect even though "exactly the same *conduct* that violated federal device requirements violated [the] state law dut[y]." Caplinger Br. 32. Nonetheless, that would hardly render the underlying state and federal *requirements* identical.

The same hypothetical confirms the underinclusiveness of the district court's "test" (assuming that was what it was). Under that test, the state and federal requirements are not identical only if "a [device] manufacturer could be held liable under the state law without [violating] the federal law." JA 50 (internal quotation marks omitted). But in the foregoing hypothetical, that test is *not* satisfied –

because the manufacturer's conduct violating state law would also violate federal law – and yet the state and federal requirements *plainly are not identical*. To be sure, the district court's "test" will be met in many cases where there is a lack of genuine equivalence. Suppose in the foregoing hypothetical, for example, that the manufacturer builds the device with a *four-inch* wire. That would lead to liability under state law for design defect but not to any violation of the federal no-longer-than-five-inch requirement. In this scenario, then, the "manufacturer could be held liable under the state law without [having violated] the federal law." JA 50 (internal quotation marks omitted). The fact that the statutory phrase "different from, or in addition to" is *not* synonymous with "requiring conduct not violating federal law" is confirmed by the text of Section 360k itself. As noted above (at page 6, *supra*), the express preemption clause nullifies "any" state "requirement" that is "different from, or in addition to," any applicable federal requirement, so long as the state requirement "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). The preemption clause thus covers, and

nullifies, any nonidentical state requirements. The exemption clause, in contrast, authorizes the FDA to select from those nonidentical state requirements two kinds that are eligible for exemptions. First, nonidentical state requirements may be exempted if they are "more stringent." 21 U.S.C. § 360k(b)(1). Second, nonidentical state requirements may be exempted if they are "(A) . . . required by compelling local conditions" and if "(B) compliance with the requirement would *not cause the device to be in violation of any applicable requirement under this chapter*." 21 U.S.C. § 360k(b)(2) (emphasis added). The inclusion of the latter requirement (§ 360k(b)(2)(B)) would not have been necessary if "different from, or in addition to," *already* meant "requiring conduct not violating federal law."

Returning to the hypothetical discussed above helps to illustrate how these provisions operate together. Because the no-more-than-three-inch-wire state law requirement is manifestly different from the no-more-than-five-inch-wire PMA requirement, the preemption clause clearly would nullify the state requirement in the absence of an exemption. But an exemption could be available under 21 U.S.C. § 360k(b)(1) if the state requirement is determined to be more stringent.

And an exemption under Section 360k(b)(2) would be possible if the less-than-three-inch-wire requirement imposed by state tort law could be shown to be required by compelling local conditions and if "compliance" with it "would not cause the device to be in violation of any applicable requirement under this chapter." This reading gives meaning to all of the various components of the preemption scheme chosen by Congress and avoids the anomalies identified above that flow from Caplinger's proposed interpretation.

To be sure, in many cases involving nonidentical state and federal requirements, it will be true that "a [device] manufacturer could be held liable under the state law without having violated the federal law" (JA 50). Thus, the "test" used by the district court will identify some situations (but not all) where state and federal requirements differ. In other words, the district court's formulation was underinclusive, although it led to the correct conclusion in this case: the state requirements Caplinger sought to impose on the Infuse device were not identical to the federal requirements. In affirming that result, however, this Court should make clear that the proper judicial focus is on a comparison of the respective state and federal *requirements*, and the

need to demonstrate that they are identical, not on whether the defendant's underlying conduct violates federal law in addition to state law.

B. Plaintiffs Should Be Required To Specify In Their Complaint Any Allegedly Identical State And Federal Requirements

In dismissing Caplinger's claims as expressly preempted, the district court explained that, in order to "'properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated.'" JA 50 (quoting *Wolicki-Gables* v. *Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (8th Cir. 2011)). And in dismissing Caplinger's negligence claim, the district court faulted the complaint for failing to allege "sufficient facts to survive a motion to dismiss." JA 68. The court explained:

> Plaintiff "cannot simply incant the magic words Medtronic violated FDA regulations in order to avoid preemption." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) (internal quotations and citation omitted). Merely alleging the defendants failed to use reasonable care "by not complying with federal law and regulations applicable to the sale and marketing" of the Infuse device is insufficient to overcome the preemptive reach of § 360k(a) without some factual detail as to how defendants violated the federal regulations.

JA 68-69.

The district court was correct to require of Caplinger's complaint both "factual detail" and specific identification of any allegedly identical state and federal requirements applicable to the Infuse device. As Medtronic correctly points out (Br. 41-43), these modest pleading requirements find support in the decisions of other courts as well as in the Supreme Court's recent decisions in *Iqbal* and *Twombly*. What is more, Congress's intent to sweep back state law claims and regulation and the value of preemption to medical device manufacturers such as Medtronic would be seriously eroded if the issue were not resolvable at the threshold of litigation based on the allegations in the complaint. PLAC urges this Court to provide greater guidance to the lower courts on this point, which arises in a variety of other preemption settings and thus is important to PLAC's members.[7]

---

[7] Many other express preemption clauses nullify state standards but only if they are "different from, or in addition to" applicable federal standards. See, *e.g.*, Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136v(b) (states may not "impose or continue in effect any requirements for labeling and packaging in addition to or different from those required under this subchapter"); Pork Promotion, Research and Consumer Information Act, 7 U.S.C. § 4817(b) ("in addition to or different from"); Egg Product Inspection Act, 21 U.S.C. § 1052(b) ("in addition to or different than"); Poultry Products Inspection Act, 21 U.S.C. § 467e ("in addition to, or different than"); Federal Meat Inspection Act, 21 U.S.C. § 678 (same). See also FDA Modernization

Finally, PLAC notes that without the requirement that a plaintiff *specifically* identify any state and federal requirements alleged to be parallel, a plaintiff could often fall back on a highly generalized formulation of the state- and federal-law requirements implicated by her complaint in an effort to conjure up equivalence or parallelism where none actually exists. Thus, if a plaintiff could merely assert that the design of a PMA-approved device is "unsafe" or its labeling is "inadequate," it would be fairly easy to identify supposedly identical federal requirements requiring labeling to be adequate and device designs safe. Indeed, the example of an obvious discrepancy in requirements given by Justice Breyer in his *Lohr* concurrence (a federal requirement of a two-inch wire in hearing aids versus a state requirement of one-inch wires) could have been made to disappear merely by climbing the ladder of abstraction and asserting in the complaint that the federal and state requirements both require a "safe" design. Yet allowing such an approach would plainly run afoul of the Supreme Court's admonition that preemption cannot be avoided with

---

Act of 1997, 21 U.S.C. § 379r(a)(2) ("different from or in addition to, or that is otherwise not identical with"); FDA Modernization Act of 1997, 21 U.S.C. § 379s(a) (same).

the stroke of a plaintiff's pen. See, *e.g.*, *Aetna Health Inc.* v. *Davila*, 542 U.S. 200, 214 (2004) ("[D]istinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would 'elevate form over substance and allow parties to evade' the pre-emptive scope of ERISA simply 'by relabeling their contract claims as claims for tortious breach of contract.'") (quoting *Allis-Chalmers Corp.* v. *Lueck*, 471 U.S. 202, 211 (1985)); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981) ("[C]ompliance with the intent of Congress cannot be avoided by mere artful pleading.").

CONCLUSION

For the foregoing reasons, as well as those set forth in Medtronic's brief, the judgment should be affirmed.

Respectfully submitted.

Hugh F. Young, Jr.
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, VA 20191
(703) 264-5300
Of Counsel

/s Alan Untereiner
Alan Untereiner
Counsel of Record
Donald Burke
ROBBINS, RUSSELL, ENGLERT, ORSECK, UNTEREINER & SAUBER LLP
1801 K Street, N.W.
Washington, DC 20006
(202) 775-4500
auntereiner@robbinsrussell.com

Counsel for the Amicus Curiae

Dated: October 22, 2013

APPENDIX A:
CORPORATE MEMBERS OF THE
PRODUCT LIABILITY ADVISORY COUNCIL

3M
Altec, Inc.
Altria Client Services Inc.
Anadarko Petroleum Corporation
AngioDynamics
Ansell Healthcare Products LLC
Astec Industries
Bayer Corporation
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
Boehringer Ingelheim Corporation
The Boeing Company
Bombardier Recreational Products, Inc.
Bridgestone Americas, Inc.
Brown-Forman Corporation
Caterpillar Inc.
CC Industries, Inc.
Celgene Corporation
Chrysler Group LLC
Cirrus Design Corporation
CNH America LLC
Continental Tire the Americas LLC
Cooper Tire & Rubber Company
Crane Co.
Crown Cork & Seal Company, Inc.
Crown Equipment Corporation
Daimler Trucks North America LLC
Deere & Company
Delphi Automotive Systems
Discount Tire
The Dow Chemical Company
E.I. duPont de Nemours and Company
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, LLC
Exxon Mobil Corporation
Ford Motor Company
General Electric Company
General Motors LLC
Georgia-Pacific Corporation
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works Inc.
Isuzu Motors America, Inc.
Jaguar Land Rover North America, LLC
Jarden Corporation
Johnson & Johnson
Kawasaki Motors Corp., U.S.A.
KBR, Inc.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Lincoln Electric Company
Lorillard Tobacco Co.

Magna International Inc.
Marucci Sports, L.L.C.
Mazak Corporation
Mazda Motor of America, Inc.
Medtronic, Inc.
Merck & Co., Inc.
Meritor WABCO
Michelin North America, Inc.
Microsoft Corporation
Mine Safety Appliances Company
Mitsubishi Motors North America, Inc.
Mueller Water Products
Mutual Pharmaceutical Company, Inc.
Navistar, Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
Novo Nordisk, Inc.
PACCAR Inc.
Panasonic Corporation of North America
Peabody Energy
Pella Corporation
Pfizer Inc.
Pirelli Tire, LLC
Polaris Industries, Inc.
Porsche Cars North America, Inc.
Purdue Pharma L.P.
RJ Reynolds Tobacco Company
SABMiller Plc
Schindler Elevator Corporation
SCM Group USA Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Stanley Black & Decker, Inc.
Subaru of America, Inc.
Techtronic Industries North America, Inc.
Teva Pharmaceuticals USA, Inc.
TK Holdings Inc.
Toyota Motor Sales, USA, Inc.
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen Group of America, Inc.
Volvo Cars of North America, Inc.
Wal-Mart Stores, Inc.
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a), I hereby hereby certify as follows:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and because it contains 6,478 words, excluding the parts of the brief exempted by Fed. R. App. R. 32(a)(7)(B)(iii); and

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced type-face using Microsoft Word 2010 in 14-point Century Schoolbook.

Dated: October 22, 2013

/s Alan Untereiner
Alan Untereiner
Counsel for the Amicus Curiae

CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that: (1) all required privacy redactions have been made; (2) the native PDF format version of this brief that was filed using the ECF filing system is an exact copy of the hard copies of this brief that are being submitted to the Clerk; and (3) the native PDF format version of this brief that was filed using the ECF filing system was scanned for viruses with the most recent version of TREND MICRO OfficeScan (version 10.6.3205 service pack 2, virus definitions last updated on October 22, 2013), and, according to that program, is free of viruses.

Dated: October 22, 2013.

/s Alan Untereiner
Alan Untereiner
Counsel for the Amicus Curiae

CERTIFICATE OF SERVICE

I hereby certify that on October 22, 2013, I electronically filed the foregoing brief using the Court's CM/ECF system, which will serve copies on the following counsel for the parties:

Michael K. Brown
James C. Martin
Lisa M. Baird
Reed Smith LLP
355 South Grand Ave.,
Suite 2900
Los Angeles, CA 90071
(213) 457-8000

Daniel L. Ring
Andrew E. Tauber
Scott M. Noveck
Mayer Brown LLP
1999 K Street, N.W.
Washington, DC 20006
(202) 263-3000

Counsel for Defendants-Appellees

James W. Dobbs
Rhodes Dobbs & Stewart,
PLLC
921 NW 164th Street, Suite B
Edmond, OK 73012
(405) 216-5100

Allison M. Zieve
Scott L. Nelson
Public Citizen Litigation Group
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

Counsel for Plaintiff-Appellant

I further certify that I caused seven paper copies of the foregoing brief to be filed with the Clerk of Court within two business days.

Dated: October 22, 2013

/s Alan Untereiner
Alan Untereiner
Counsel for the Amicus Curiae